

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Pop Kab LLC
d/b/a Pops Grocery,

Respondent.

Docket No. C-13-718
FDA Docket No. FDA-2013-H-0513

Decision No. CR2847

Date: July 2, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Pop Kab LLC d/b/a Pops Grocery, alleging facts and legal authority sufficient to justify the imposition of a civil money penalty of \$250. Respondent did not timely answer the Complaint, nor did Respondent request an extension of time within which to file an Answer. Therefore, I enter a default judgment against Respondent and assess a civil money penalty of \$250.

CTP began this case by serving the Complaint on Respondent and filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that Respondent impermissibly sold tobacco products to a minor, failed to verify that a purchaser of cigarettes or smokeless tobacco was 18 years of age or older and sold individual cigarettes, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C.

§ 301 *et seq.*, and its implementing regulations, Cigarettes and Smokeless Tobacco, 21 C.F.R. Part 1140 (2012). CTP seeks a civil money penalty of \$250.

On May 6, 2013, CTP served the Complaint on Respondent by United Parcel Service, pursuant to 21 C.F.R. §§ 17.5 and 17.7. In the Complaint and accompanying cover letter, CTP explained that within 30 days, Respondent should pay the proposed penalty, file an answer, or request an extension of time within which to file an answer. CTP warned Respondent that if it failed to take one of these actions within 30 days, an Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering Respondent to pay the full amount of the proposed penalty.

Respondent has not filed an answer within the time provided by regulation, nor has it timely requested an extension. Pursuant to 21 C.F.R. § 17.11(a), I am required to “assume the facts alleged in the [C]omplaint to be true” and, if those facts establish liability under the Act, issue a default judgment and impose a civil money penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns Pops Grocery, an establishment that sells tobacco products and is located at 267 Grand Avenue, New Haven, Connecticut 06513. Complaint ¶ 2.
- On July 2, 2012, at approximately 1:33 PM, an FDA-commissioned inspector observed two violations at Respondent’s establishment. The inspector observed a violation of 21 C.F.R. § 1140.14(a), a regulation prohibiting the sale of cigarettes or smokeless tobacco to a person younger than 18 years of age. The inspector also observed a violation of 21 C.F.R. § 1140.14(b)(1), a regulation requiring retailers to verify, by means of photo identification containing a purchaser’s date of birth, that no purchaser of cigarettes or smokeless tobacco is younger than 18 years of age. Complaint ¶ 9.
- On July 11, 2012, CTP issued a Notice of Compliance Check Inspection to Respondent, “stating that an inspection had been conducted on July 2, 2012, and that during this inspection a minor was able to enter the establishment and purchase a regulated tobacco product at approximately 1:33 PM.” The Notice further indicated that the violation was not necessarily the only violation observed. Complaint ¶ 9.

- On September 13, 2012, CTP issued a Warning Letter to Respondent regarding the inspector's observations from July 2, 2012. The letter explained that the observations constituted violations of regulations found at 21 C.F.R. § 1140.14(a) and 1140.14(b)(1), and that the named violations were not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter went on to state that if Respondent failed to correct the violations, Respondent's inaction could result in a civil money penalty or other regulatory action by the FDA and that Respondent is responsible for complying with the law. Complaint ¶ 9.
- CTP received no response to the Warning Letter from Respondent, though United Parcel Service records demonstrate that an individual named "POP" received the Warning Letter on September 14, 2012. Complaint ¶ 10.
- During a two-part inspection conducted on December 24, 2012, and January 2, 2013, FDA-commissioned inspectors documented an additional violation at Respondent's establishment. The inspectors documented a violation of 21 C.F.R. § 1140.14(d) "for selling individual cigarettes." Complaint ¶ 1.

These facts establish that Respondent is liable under the Act. The Act prohibits misbranding of a tobacco product. 21 U.S.C. § 331(k). A tobacco product is misbranded if distributed or offered for sale in any state in violation of regulations issued under section 906(d) of the Act. 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). The Secretary issued the regulations at 21 C.F.R. Part 1140 under section 906(d) of the Act. 21 U.S.C. § 387(a); 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,229 (Mar. 10, 2010). The regulations prohibit the sale of cigarettes or smokeless tobacco to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a). The regulations also require retailers to verify, by means of photo identification containing the purchaser's date of birth, that no purchasers of cigarettes or smokeless tobacco are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Finally, the regulations prohibit retailers from "break[ing] or otherwise open[ing] any cigarette or smokeless tobacco package to sell or distribute individual cigarettes" 21 C.F.R. § 1140.14(d).

Taking the above alleged facts as true, Respondent had three violations of regulations contained in 21 C.F.R. Part 1140 within a six month period. Specifically, Respondent had two violations on July 2, 2012, and one violation during a two-part inspection conducted on December 24, 2012, and January 2, 2013. Respondent's actions violated the prohibition against selling cigarettes or smokeless tobacco to persons younger than 18 years of age. 21 C.F.R. § 1140.14(a). Respondent's actions also violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that

no purchaser of cigarettes or smokeless tobacco is younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Finally, Respondent's actions violated the prohibition against selling individual cigarettes. 21 C.F.R. § 1140.14(d). Therefore, Respondent's actions constitute violations of law for which a civil money penalty is merited.

The regulations require me to impose a civil money penalty in an amount that is either the maximum provided for by law or the amount sought in the Complaint, whichever is smaller. 21 C.F.R. § 17.11(a)(1)-(2). The regulations currently allow a maximum penalty of \$500 for a third violation within a six month period. 21 C.F.R. § 17.2. CTP, however, has requested a fine in the amount of \$250. Therefore, I find that a civil money penalty of \$250 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge